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TO : Commissioner for Patents
Mail Stop: Appeal Brief-Patent

FROM : Oleg F. Kaplun, Esq. of Fay Kaplun & Marcin, LLP

DATE : April 11, 2007

SUBJECT : U.S. Patent Appln. Serial No. 10/764,619
for *Stapling and Cutting in Resectioning for Full
Thickness Resection Devices*
Inventor(s): McAlister et al.
Our Ref.: 10121/00308

NUMBER OF PAGES INCLUDING COVER : 24

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Attorney Docket No. 10121/00308 (00-0044CON2)

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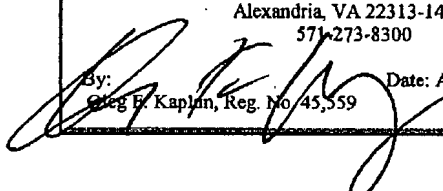
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : McAlister et al.
Serial No. : 10/764,619
Filed : January 26, 2004
For : Stapling and Cutting in Resectioning for Full Thickness
Resection Devices
Group Art Unit : 3734
Examiner : Eric S. Keasel
Confirmation No. : 8922

Mail Stop: Appeal Brief - Patent
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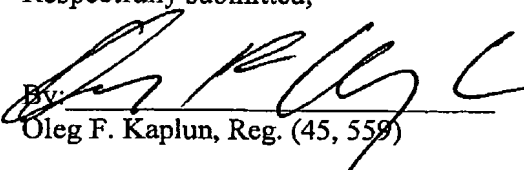
By:  Date: April 11, 2007
Oleg F. Kaplan, Reg. No. 45,559

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Respectfully submitted,

Dated: April 11, 2007


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Attorney Docket No. 10121/00308 (00-0044CON2)

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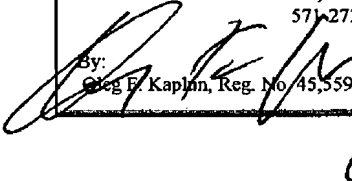
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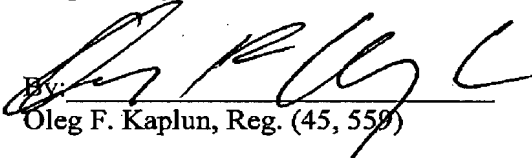
By:  Date: April 11, 2007
Greg F. Kaplun, Reg. No. 45,559

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PATENT

Attorney Docket No.: 10121 - 00308

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of:)	
)	
McAlister et al.)	
)	
Serial No.: 10/764,619)	Group Art Unit: 3734
)	
Filed: January 26, 2004)	Examiner: Michael T. Andersen
)	
For: STAPLING AND CUTTING IN)	Board of Patent Appeals and
RESECTIONING FOR FULL)	Interferences
THICKNESS RESECTION DEVICES)		

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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

In support of the Notice of Appeal filed February 20, 2007, and pursuant to 37 C.F.R. § 41.37, Appellants present an appeal brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 57 - 72 in the final Office Action dated November 29, 2006 as clarified in the Advisory Action dated February 1, 2007. The appealed claims are set forth in the attached Claims Appendix.

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Group Art Unit: 3734

Attorney Docket No.: 10121 - 00308

1. Real Party in Interest

This application is assigned to Scimed Life Systems, Inc., the real party in interest.

2. Related Appeals and Interferences

There are no other appeals or interferences which would directly affect, be directly affected, or have a bearing on the instant appeal.

3. Status of the Claims

Claims 57 - 72 have been rejected in the final Office Action, and are the subject of the present appeal.

4. Status of Amendments

All amendments submitted by the Appellants have been entered.

5. Summary of Claimed Subject Matter

The present invention comprises a device for stapling and removal of tissue within a body lumen without resorting to open surgery. (See Specification, page 4, lines 5-10).

Independent claim 57 recites a stapling unit for an endolumenal stapling system that includes a housing including a substantially tubular wall and a distal end cap. As described in the specification, a stapling unit for an endoscopic stapling system comprises a first casing formed as

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a partially tubular member. (Id. at page 4, lines 12-29; Figs. 1A - 1D). Claim 57 also recites that the housing is slidably coupleable to an endoscope for advancement therealong. According to the specification, the stapling unit may be advanced distally along the endoscope. (Id. at p. 4, lines 19-21). Claim 57 also recites that the tubular wall includes a window extending therethrough with an anvil formed on a first edge of the window. As described in the specification, a window of the first casing includes an edge forming an anvil. (Id. at p. 5, lines 3 - 5). Claim 57 also recites that the housing further includes a stapling apparatus mounted within the housing for movement between a stapling position in which a staple firing surface of the stapling apparatus is adjacent to the anvil and a tissue receiving position in which the staple firing surface is separated from the anvil to open the window and expose a tissue receiving cavity within an interior of the housing. According to the specification, the stapling unit includes a stapling device, which includes a stapling head rotatably mounted within the first casing such that the stapling head covers varying portions of the window by moving between retracted and engaged positions. (Id. at p. 5, line 9 - p. 6, line 6; Figs. 2A, 2B, 3A - 3C). Claim 57 also recites that the staple firing apparatus drives a staple out of the staple firing surface through tissue in the tissue receiving cavity. As described in the specification, the stapling head fires staples from a staple firing edge of the stapling device through tissue and against the anvil to staple the portion of tissue grasped between the staple firing edge and the anvil. (Id. at p. 6, lines 8 - 18). Claim 57 also recites that the endolumenal stapling system further includes a tissue grasping mechanism extendible through the window for drawing tissue through the window into the tissue receiving

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cavity. As described in the specification, a tissue grasper may be included within the stapling unit to draw the portion of tissue to be stapled and the portion of tissue to be cut into the window. (Id. at p. 9, lines 24 - 31).

Independent claim 68 recites a method of endolumenally resecting tissue within a body lumen comprising the step of endoscopically locating a portion of tissue to be resected within a body lumen. (Id. at p. 4, lines 12 - 21). The method of claim 68 further comprises sliding a housing along the endoscope to a desired position adjacent to the portion of tissue to be resected, the housing including a substantially tubular wall and a distal end cap. (Id. at p. 4, lines 24-29). The tubular wall includes a window extending therethrough with an anvil formed on an edge of the window. (Id. at p. 5, lines 3 - 5). The housing further includes a stapling apparatus movably mounted therewithin, the stapling apparatus opening and closing the window as it moves within the housing between a tissue receiving position and a stapling position. (Id. at p. 5, line 9 - p. 6, line 6; Figs. 2A, 2B, 3A - 3C). Claim 68 further recites moving the stapling apparatus to the tissue receiving position to open the window and drawing the portion of tissue to be resected into the housing through the window folded over so that two full thicknesses of tissue of a wall of the body lumen are received within the window. (Id. at p. 9, lines 24 - 31, Fig. 3C). Claim 68 further recites moving the stapling apparatus to the stapling position clamping the portion of tissue to be resected between the stapling apparatus and the anvil, driving staples from the stapling apparatus through the two thicknesses of wall tissue to couple the two thicknesses of wall tissue to one another, and cutting tissue radially within the stapled tissue from the stapled

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tissue. (Id. at p. 6, lines 8 - 18; p. 7, lines 4 - 18).

Independent claim 72 recites a system for endolumenally resecting tissue comprising a flexible endoscope and a housing including a substantially tubular wall including a window extending therethrough with an anvil formed on a first edge of the window and a distal end cap. (Id. at p. 4, lines 12 - 21). The housing is slidably coupled to the endoscope and includes a stapling apparatus mounted within the housing for movement between a stapling position in which a staple firing surface of the stapling apparatus is adjacent to the anvil and a tissue receiving position in which the staple firing surface is separated from the anvil to open the window and expose a tissue receiving cavity within the housing, the staple firing apparatus driving a staple out of the staple firing surface through tissue in the tissue receiving cavity. (Id. at p. 6, lines 8 - 18). Claim 72 further recites a tissue grasping mechanism extendible through the window for drawing tissue through the window into the tissue receiving cavity. (Id. at p. 9, lines 24 - 31).

6. Grounds of Rejection to be Reviewed on Appeal

- I. Whether claims 57 - 72 are unpatentable under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,037,021 to Mills et al. ("Mills") in view of U.S. Patent No. 5,947,983 to Solar et al. ("Solar")

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7. ArgumentI. The Rejection of Claims 57 - 72 Under 35 U.S.C. § 103(a) as
Being Obvious Over U.S. Patent No. 5,037,021 to Mills in view of
U.S. Patent No. 5,947,983 to Solar Should Be ReversedA. The Examiner's Rejection

In the Final Office Action, the Examiner rejected claims 57 - 72 under 35 U.S.C. 103(a) as being unpatentable over Mills in view of Solar. (See 11/29/06 Office Action, p. 2).

Mills describes a stapling machine including a body defining a cavity into which tissue is sucked. (See Mills, col. 6, lines 4 - 41). A proximal end of the machine includes a wire carrying a piston. An opposing wall of the cavity forms an anvil plate against which a staple is driven by the piston. (Id.).

Solar describes a device for cutting tissue that includes a first tube and a second tube which is coaxial and movable within the first tube. (See Solar, col. 3, lines 1 - 10). A third tube is movable within the second tube. Each of the first, second and third tubes include a window aligned with the windows of the other tubes. (Id.). The window of the third tube includes a cutting edge perpendicular to a direction of relative movement between the third tube and the first and second tubes. (Id. at col. 3, lines 12 - 29).

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- B. The Cited References do not Disclose a Stapling Apparatus Moving Between a Stapling Position with a Staple Firing Surface Adjacent to the Anvil and a Tissue Receiving Position Separated From the Anvil as Recited in Claim 57
-

The Examiner stated in the Final rejection that Mills discloses a staple firing surface "separated from the anvil to open the window and expose a tissue receiving cavity within an interior of the housing." (See 11/29/06 Office Action, pp. 2 - 3). The Examiner reaffirmed this position in the Advisory Action of 2/1/07, stating that the wire 206 and piston 205 of Mills operate to close a cavity 202 as the piston 205 is driven from a retracted to a protracted position. The Appellants respectfully disagree with this assertion. Although the cavity 202 defines an opening in which tissue is received, the cavity 202 does not constitute a window that is opened or closed. This can clearly be seen from Figs. 4e - 4h of Mills, which show bottom views of a sewing device that includes a similar tissue receiving cavity. As shown, the cavity of the device is open on lateral sides thereof. Thus, the cavity is always open in the sense that the lateral portions of the cavity 202 are never closed off or obstructed in any way. Regardless of whether a bottom portion of the cavity 202 is closed or not, the cavity 202 is always open by virtue of being unenclosed on either side. Furthermore, there is nothing to suggest that the piston 205 is capable of closing off the bottom opening of the cavity 202. Mills provides no suggestion whatsoever that a width of the piston 205 is sufficient to fully cover the bottom opening (e.g., from one lateral side of the device to the opposing lateral side).

In addition, the anvil of Mills is located on an inner wall of the cavity 202 separated from

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the outer edge of the housing where any window would be located. In contrast, claim 57 recites that an anvil is "formed on a first edge of the window." Claim 57 also recites that the staple firing surface opens the window in order to expose a tissue receiving cavity. Thus, the cavity and the window are distinct elements. It is not the cavity itself which opens and closes, but rather a window that provides access to the cavity. Therefore, the cavity 202 cannot be both a tissue receiving cavity and a window.

Based on these reasons, it is respectfully submitted that no portion of the cavity 202 constitutes a window and that Mills neither discloses nor suggests "a tissue receiving position in which the staple firing surface is separated from the anvil to open the window and expose a tissue receiving cavity within an interior of the housing," as recited in claim 57.

In addition, because the only purpose of the piston 205 is to drive the staple rather than to effect a closing of the opening, there is no reason to position the piston 205 adjacent to the anvil. As seen in Fig. 5c of Mills, the piston 205 is capable of closing the staple without being pushed all the way across the opening. This is because the piston 205 contacts a proximal end of the staple well in advance of reaching a distal end of the opening. The piston 205 does not act on the tissue being stapled, but rather, as seen in Fig. 5c, leaves a substantial amount of space between the tissue and the distal end of the cavity. Thus, the piston 205 is never adjacent to the anvil. In contrast, the specification of the present invention states that in the stapling position, the staple head covers a large portion of the window so that a portion of tissue received in the window is grasped between the staple firing edge and the anvil. (See Specification, p. 6, lines 3 - 6).

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Whereas adjacency affects the ability of the present invention to grasp tissue, Mills never teaches or suggests grasping the tissue during stapling. Thus, it is respectfully submitted that Mills neither discloses nor suggests "a stapling apparatus mounted within the housing for movement between a stapling position in which a staple firing surface of the stapling apparatus is adjacent to the anvil," as recited in claim 57.

The Examiner also contends that the recitation "driving a staple out of" can be construed as meaning "out of contact." (See 2/1/07 Advisory Action). However, the Appellants respectfully submit that this assertion is inconsistent with a proper reading of the recited limitation. It is respectfully submitted that the limitation "driving a staple out of the staple firing surface" clearly indicates that the staples are initially located within the firing surface. Even given its broadest possible meaning, the term "out of" would still imply an initial state of being "within." It is submitted that the Examiner's reading of this term is similar to interpreting the phrase "driving a car out of the garage" as including the driving of a car parked outside the garage further away from the garage when it clearly indicates that the car is driven from inside the garage to outside the garage. In this example, the car is initially within the garage before being driven away from (i.e., out of) the garage. Numerous additional examples of this term are found in everyday usage, including "walking out of a room," "running out of bounds" and "pulling an object out of a box." In each of these examples, it is understood that in the process of performing some action (driving, walking, running, etc.) on an object, a status of the object is changed from an initial state of being within a second object or location, to a new state of being

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outside of the second object/location. It is respectfully submitted that no additional language is needed to clarify this meaning and it is respectfully submitted that the Examiner's reading of claim 57 adds extra words that give new and unnecessary meaning to an otherwise well-defined limitation. For these reasons it is submitted that Mills neither shows nor suggests a "staple firing apparatus driving a staple out of the staple firing surface through tissue in the tissue receiving cavity," as recited in claim 57.

The Appellants further submit that Solar fails to cure the deficiencies of Mills. In particular, Solar describes a cutting device and is completely unrelated to the stapling of tissue. Solar only describes the suturing of tissue after the tissue is cut. The suturing is performed using a needle that is distally advanced through the second tube by rotating the needle. (See Solar, col. 3, line 50 - col. 4, line 15). Thus, it is respectfully submitted that neither Mills nor Solar, either alone or in combination, discloses or suggests "a stapling apparatus mounted within the housing for movement between a stapling position in which a staple firing surface of the stapling apparatus is adjacent to the anvil and a tissue receiving position in which the staple firing surface is separated from the anvil to open the window and expose a tissue receiving cavity within an interior of the housing, the staple firing apparatus driving a staple out of the staple firing surface through tissue in the tissue receiving cavity," as recited in claim 57.

Therefore, at least for these reasons, it is respectfully submitted that claim 57 is allowable. Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. 103(a) of independent claim 57 and all the claims depending directly or

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indirectly therefrom (claims 58 - 67)

Independent claim 72 was also rejected under 35 U.S.C. § 103(a) as unpatentable over Mills in view of Solar. Claim 72 recites limitations substantially similar to claim 57 including “a stapling apparatus mounted within the housing *for movement between a stapling position in which a staple firing surface of the stapling apparatus is adjacent to the anvil and a tissue receiving position in which the staple firing surface is separated from the anvil to open the window and expose a tissue receiving cavity within the housing*, the staple firing apparatus *driving a staple out of the staple firing surface* through tissue in the tissue receiving cavity.”

Thus, it is respectfully submitted that claim 72 is allowable for at least the reasons discussed above with regard to claim 57. The Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 103(a) of independent claim 72.

Independent claim 68 was also rejected under 35 U.S.C. § 103(a) as unpatentable over Mills in view of Solar. Claim 68 recites a method of endolumenally resecting tissue within a body lumen comprising the steps of “endoscopically locating a portion of tissue to be resected within a body lumen” and “sliding a housing along the endoscope to a desired position adjacent to the portion of tissue to be resected, the housing including a substantially tubular wall and a distal end cap, the tubular wall including a window extending therethrough with an anvil formed on an edge of the window, the housing further including a stapling apparatus movably mounted therewithin, *the stapling apparatus opening and closing the window as it moves within the housing between a tissue receiving position and a stapling position*” in combination with

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“moving the stapling apparatus to the tissue receiving position to open the window” and
“drawing the portion of tissue to be resected into the housing through the window folded over so that two full thicknesses of tissue of a wall of the body lumen are received within the window”
and *“moving the stapling apparatus to the stapling position clamping the portion of tissue to be resected between the stapling apparatus and the anvil”* in combination with *“driving staples from the stapling apparatus through the two thicknesses of wall tissue to couple the two thicknesses of wall tissue to one another”* and *“cutting tissue radially within the stapled tissue from the stapled tissue.”*

Thus, it is respectfully submitted that claim 68 is allowable for at least the reasons discussed above with regard to claim 57. The Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 103(a) of independent claim 68 and all claims depending directly or indirectly therefrom (claims 69 - 71).

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9. Conclusions

For the reasons set forth above, Appellants respectfully request that the Board reverse the final rejections of the claims by the Examiner under 35 U.S.C. § 103(a) and indicate that claims 57 - 72 are allowable.

Respectfully submitted,

Date: April 11, 2007

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CLAIMS APPENDIX

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57. (Rejected) A stapling unit for an endolumenal stapling system comprising:

a housing including a substantially tubular wall and a distal end cap, the housing being slidably coupleable to an endoscope for advancement therealong, the tubular wall including a window extending therethrough with an anvil formed on a first edge of the window, the housing further including a stapling apparatus mounted within the housing for movement between a stapling position in which a staple firing surface of the stapling apparatus is adjacent to the anvil and a tissue receiving position in which the staple firing surface is separated from the anvil to open the window and expose a tissue receiving cavity within an interior of the housing, the staple firing apparatus driving a staple out of the staple firing surface through tissue in the tissue receiving cavity; and

a tissue grasping mechanism extendible through the window for drawing tissue through the window into the tissue receiving cavity.

58. (Rejected) The stapling unit according to claim 57, further comprising:

a control handle which, when the housing is in an operative position within a body lumen, remains outside the body; and

a flexible sheath extending from the control handle to a proximal end of the housing.

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59. (Rejected) The stapling unit according to claim 58, wherein the flexible sheath has a column strength sufficient to allow an operator to push the housing along an endoscope into a body lumen by pushing the flexible sheath into the body lumen.

60. (Rejected) The stapling unit according to claim 57, wherein the stapling apparatus is mounted within the housing for rotation about an axis of the housing between the stapling and tissue receiving positions.

61. (Rejected) The stapling unit according to claim 57, wherein the stapling apparatus is mounted within the housing for motion substantially parallel to a longitudinal axis of the housing.

62. (Rejected) The stapling unit according to claim 57, wherein the housing includes an endoscope receiving lumen extending thereinto from a proximal opening to a distal opening formed in the distal end cap.

63. (Rejected) The stapling unit according to claim 62, further comprising:

- a control handle which, when the housing is in an operative position within a body lumen, remains outside the body; and
- a flexible sheath extending from the control handle to a proximal end of the housing, wherein in an operative configuration, an endoscope is slidably received within

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the endoscope receiving lumen of the housing and extends through the sheath to the control handle.

64. (Rejected) The stapling unit according to claim 57, further comprising:

a tissue cutting mechanism mounted within the housing for cutting tissue located radially within a portion of tissue stapled by the stapling apparatus.

65. (Rejected) The stapling unit according to claim 64, wherein the tissue cutting mechanism includes a partially cylindrical member rotatably mounted within the housing radially within the stapling apparatus and including an angled tissue cutting surface.

66. (Rejected) The stapling unit according to claim 57, wherein the stapling apparatus is mounted within the housing to rotate about an axis thereof across the window.

67. (Rejected) The stapling unit according to claim 57, wherein the stapling apparatus is mounted within the housing to move along an axis thereof across the window.

68. (Rejected) A method of endolumenally resecting tissue within a body lumen, comprising the steps of:

endoscopically locating a portion of tissue to be resected within a body lumen;

sliding a housing along the endoscope to a desired position adjacent to the portion

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of tissue to be resected, the housing including a substantially tubular wall and a distal end cap, the tubular wall including a window extending therethrough with an anvil formed on an edge of the window, the housing further including a stapling apparatus movably mounted therewithin, the stapling apparatus opening and closing the window as it moves within the housing between a tissue receiving position and a stapling position;

moving the stapling apparatus to the tissue receiving position to open the window;

drawing the portion of tissue to be resected into the housing through the window folded over so that two full thicknesses of tissue of a wall of the body lumen are received within the window;

moving the stapling apparatus to the stapling position clamping the portion of tissue to be resected between the stapling apparatus and the anvil;

driving staples from the stapling apparatus through the two thicknesses of wall tissue to couple the two thicknesses of wall tissue to one another; and

cutting tissue radially within the stapled tissue from the stapled tissue.

69. (Rejected) The method according to claim 68, wherein the stapling apparatus is rotated within the housing between the tissue receiving and stapling positions.

70. (Rejected) The method according to claim 68, wherein the stapling apparatus is moved longitudinally within the housing between the tissue receiving and stapling positions.

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71. (Rejected) The method according to claim 68, wherein the housing is coupled to a control handle which remains outside the body by a flexible sheath and wherein the operative housing is slid along the endoscope by pushing the flexible sheath into the body lumen.

72. (Rejected) A system for endolumenally resecting tissue comprising:

a flexible endoscope;

a housing including a substantially tubular wall including a window extending therethrough with an anvil formed on a first edge of the window and a distal end cap, the housing being slidably coupled to the endoscope and including a stapling apparatus mounted within the housing for movement between a stapling position in which a staple firing surface of the stapling apparatus is adjacent to the anvil and a tissue receiving position in which the staple firing surface is separated from the anvil to open the window and expose a tissue receiving cavity within the housing, the staple firing apparatus driving a staple out of the staple firing surface through tissue in the tissue receiving cavity; and

a tissue grasping mechanism extendible through the window for drawing tissue through the window into the tissue receiving cavity.

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EVIDENCE APPENDIX

No evidence has been submitted herewith or is relied upon in the present appeal.

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Serial No.: 10/764,619

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RELATED PROCEEDINGS APPENDIX

There are no related proceedings and/or decisions which relate to the present appeal.